Part 11

Electronic Records; Electronic Signatures

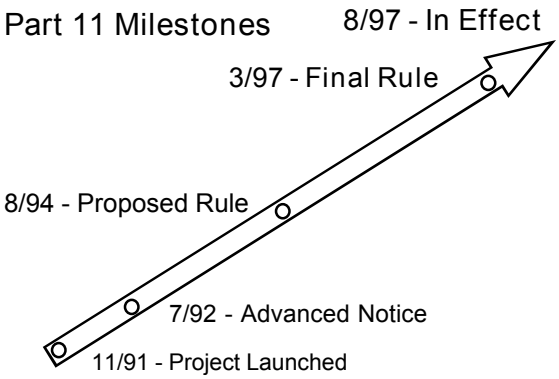
The Final Rule

P. Motise

We will cover Part 11

- Milestones
- Overall approach
- Provisions
- What industry needs to do

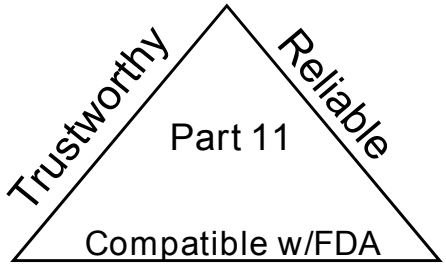
Part 11 Milestones



Part 11, Purpose

- Accept/promote new technologies
- Benefit industry & FDA
  - Operational efficiencies
  - Paperwork reduction
- Keep ability to promote/protect public health

E-Record/E-Sig Acceptance



Public Health Responsibilities

Part 11 Subparts

A - General

B - Electronic Records

C - Electronic Signatures

Part 11 Subparts

A - General

B - Electronic Records

C - Electronic Signatures

§ 11.1 Scope

- Criteria making E-sig/E-record
  - Trustworthy
  - Reliable
  - Equivalent to H-sig/Paper

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§ 11.1 Scope

- Part 11 Compliance = E-sig Acceptance
  - All signings
    - Full signatures, initials, etc.
  - All FDA regulations
  - Exceptions by future regs

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§ 11.1 Scope

- E-records
  - All FDA regulations
  - Submissions per FD&C/PHS Acts
  - Unless reg. demands paper (future)
- Not paper sent electronically

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§ 11.1 Scope

- FDA inspection
  - Computer Systems
    - Includes Hardware/Software
  - Controls
  - Documentation

§ 11.2 Implementation

- Maintenance records - need
  - Part 11 compliance
- Submissions records - need
  - Part 11 compliance; AND
  - Record in Docket 92S-0251

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§ 11.2 Implementation

- Submissions Docket 92S-0251
  - Record
  - Authority (reg/law)
  - FDA receiving unit/contact
  - Optional info and guidance
    - Archiving/logistics

§ 11.3 Definitions

- Electronic record

"any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system."

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§ 11.3 Definitions

- Electronic signature

"a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalentof the individual's handwritten signature."

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§ 11.3 Definitions

- Handwritten signature

"the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form."

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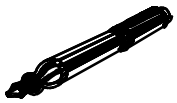
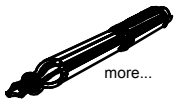


§ 11.3 Definitions

- Handwritten signature

"The act of signing with a writing ormarking instrument such as a pen or stylusis preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark."



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§ 11.3 Definitions

- Digital signature

"an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified."

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§ 11.3 Definitions

- Biometrics

"a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable."

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§ 11.3 Definitions

- Closed system

"an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system."

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§ 11.3 Definitions

- Open system

"an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system."

Part 11 Subparts

A - General

B - Electronic Records

C - Electronic Signatures

§ 11.10 Controls for closed systems

- Controls designed to ensure:
  - Authenticity
  - Integrity
  - Confidentiality (as appropriate)
  - Against signer ready repudiation

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§ 11.10 Controls for closed systems

- Validation, to ensure
  - Accuracy/reliability
  - Consistent intended performance
  - Discern invalid/altered records

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§ 11.10 Controls for closed systems

- Ability to make copies that are:
  - Accurate and complete
  - Human readable and electronic
    - Suitable for FDA review/copying

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§ 11.10 Controls for closed systems

- Archiving:
  - Accurate/ready retrieval throughout retention period
- System access limitation
  - Only authorized individuals

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§ 11.10 Controls for closed systems

- Audit trails that are:
  - Secure
  - Operator independent
  - Computer generated
  - Time-stamped (date & time)

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§ 11.10 Controls for closed systems

- Audit trails must cover:
  - Operator entries/actions that cause e-record
    - Creation
    - Modification
    - Deletion

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§ 11.10 Controls for closed systems

- Audit trail documentation:
  - Retain per base e-record
  - Available for FDA review/copying
- Record changes not to obsure prior info

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§ 11.10 Controls for closed systems

- Operational system checks, as appropriate to:
  - Enforce step/event sequencing

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§ 11.10 Controls for closed systems

- Authority checks on individuals
  - System use
  - Signing
  - Operational access/performance
  - Input/output device access

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§ 11.10 Controls for closed systems

- Device checks, as appropriate
  - Validity of source
    - Operational instruction
    - Data input

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§ 11.10 Controls for closed systems

- Personnel qualifications
  - Education, training & experience
  - People who develop, maintain, or use
    - E-record/e-sig systems

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§ 11.10 Controls for closed systems

- Accountability policies
  - Written & followed
  - Hold people accountable/responsible for actions under e-sigs
    - Deter record/signature falsification

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§ 11.10 Controls for closed systems

- Control systems documentation
  - Operation/maintenance docs.
    - Distribution, access & use
  - Change control
    - Audit trail of modifications

§ 11.30 Controls for open systems

- Designed to ensure e-record:
  - Authenticity
  - Integrity
  - Confidentiality, as appropriate
- From creation to receipt

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§ 11.30 Controls for open systems

- Include §11.10 controls, as appropriate:
- Added measures, per circumstances, to ensure:
  - Authenticity, Integrity
  - Confidentiality, as appropriate

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§ 11.30 Controls for open systems

- Examples of added measures:
  - Document encryption
  - Digital signatures

§ 11.50 Signature manifestations

- Info associated w/E-record must clearly show:
  - Signer's printed name
  - Date/time of signing
  - Meaning of signature
    - E.g., review, approval

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§ 11.50 Signature manifestations

- Signature info:
  - Subject to e-record controls
  - Part of e-record human readable form
    - Electronic display
    - Printout

§ 11.70 Signature/record linking

- Link to ensure sigs can't be:
  - Excised
  - Copied
  - Otherwise transferred
- Prevent e-record falsification by ordinary means

Part 11 Subparts

A - General

B - Electronic Records

C - Electronic Signatures

§ 11.100 General Requirements (E-Sigs)

- Unique to one individual
  - No reuse by someone else
  - No reassignment

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§ 11.100 General Requirements (E-Sigs)

- Verify individual ID before e-sig (or e-sig element) is:
  - Established
  - Assigned
  - Certified
  - Otherwise sanctioned

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§ 11.100 General Requirements (E-Sigs)

- Certification to FDA:
  - What - Intent
    - E-sigs = H-sigs, legally binding
  - When - Pronto
    - Before, or at time of, e-sig use
      - First, but Not each use

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§ 11.100 General Requirements (E-Sigs)

- Certification to FDA:
  - How - Paper letter
    - Over h-sig
  - Where - FDA HQ
    - Office of Regional Operations
      - HFC-100, Rockville, MD 20857

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§ 11.100 General Requirements (E-Sigs)

- Certification to FDA:
  - Scope - Global:
    - One per enterprise
  - More - Per FDA request re. specific e-sig:
    - Certification or testimony

Pursuant to §11.100 of Title 21 of the Code of Federal Regulations, this is to certify that {organization name} intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures.

§ 11.200 E-sig components and controls

- Non-biometric e-sig:
  - Two distinct components:
    - E.g., User ID and password

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§ 11.200 E-sig components and controls

- Non-biometric e-sig:
  - Multi-signings, one continuous controlled access:
    - 1st signing: all components
    - 2nd+ signing: ≥ 1 component:
      - designed for signer's use only
      - executable by signer only

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§ 11.200 E-sig components and controls

- Non-biometric e-sig:
  - Multi-signings NOT in one continuous controlled access:
    - each signing: all components

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§ 11.200 E-sig components and controls

- Non-biometric e-sig:
  - Used only by genuine owners
  - Attempted use by others (Part 11 doesn't sanction such use.)
  - Multilateral collaboration needed

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§ 11.200 E-sig components and controls

- Biometric e-sig:
  - Designed to ensure use only by genuine owners

§ 11.300 Controls for id codes/passwords

- Persons must use controls to ensure security & integrity
- Unique ID/PW combo:
  - No 2 people have same ID/PW

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§ 11.300 Controls for id codes/passwords

- Periodically check, recall, or revise issuance
  - E.g., address pw aging

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§ 11.300 Controls for id codes/passwords

- Loss management procedures
  - Deauthorize potentially compromised devices that:
    - Bear/generate id/pw info
  - Issue replacements
    - Use suitable, rigorous controls

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§ 11.300 Controls for id codes/passwords

- Unauthorized use safeguards
  - Report attempts in urgent & immediate manner to:
    - Security unit
    - Management, as appropriate

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§ 11.300 Controls for id codes/passwords

- Initial & periodic device testing
  - Things that bear/generate
    - Id/pw info
  - Test for:
    - Proper functioning
    - Unauthorized alterations

What industry needs to do

- Learn Part 11
- File 11.100(c) Certification
- E-records maintained
  - ID formats FDA can audit/copy
    - Check w/FDA auditors
    - Watch for guidance docs

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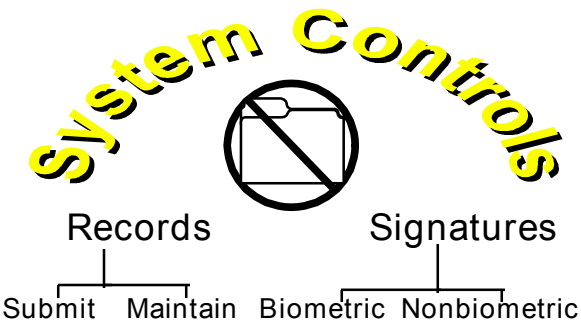
What industry needs to do

- E-records submitted to FDA
  - Check docket 92S-0251
    - http://www.fda.gov
  - Attn: logistics and guidance
    - File format/media
    - Transmission methods/archiving



Part 11 Internet Web Site:

http://www.fda.gov/cder/esig/part11.htm

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